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10/759,377	01/16/2004	Valerie J. Ryan	1022.1157-013	6714
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HAMILTON, BROOK, SMITH & REYNOLDS, P.C.			HUYNH, CARLICK K	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/759,377	<b>Applicant(s)</b> RYAN ET AL.
	<b>Examiner</b> CARLIC K. HUYNH	<b>Art Unit</b> 1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 December 2007.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 19-26, 29-33 and 35-48 is/are pending in the application.
- 4a) Of the above claim(s) 19-26 and 29-33 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 35-48 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt of applicants' amendments and remarks filed on December 10, 2007 is acknowledged.

#### ***Status of the Claims***

1. Claims 19-26, 29-33, and 35-48 are pending in the application, with claims 19-26 and 29-33 having been withdrawn, in response to the restriction requirement filed on July 25, 2007. Accordingly, claims 35-48 are being examined on the merits herein.

The rejections under 35 U.S.C. 103 to claims 35-48 as being unpatentable over Hartigan et al. (US 5,709,896 as cited in the IDS) in view of Wolf et al. (US 6,774,111) have been withdrawn in view of Applicants' amendments.

Claims 35-48 are directed to a composition and thus intended use is not given any patentable weight.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 35-48 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for maltodextrin, hydrolyzed guar gum, inulin, Larch Gum, Gum Arabic, and Benefiber as polysaccharides of molecular weights from about 1,000 to about 50,000

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daltons, does not reasonably provide enablement for any other polysaccharide having molecular weight from about 1,000 to about 50,000 daltons. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without *undue experimentation*. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547, the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1). **Nature of the Invention:**

The rejected claim(s) is/are drawn to an invention which pertains to a low viscosity glucomannan composition comprising glucomannan and an edible viscosity lowering polysaccharide.

(2). **State of the Prior Art:**

The skilled artisan would recognize that not all polysaccharides having a molecular weight from about 1,000 to about 50,000 daltons can lower viscosity.

(3). **Relative Skill of Those in the Art:**

The relative skill of those in the art of viscosity lowering polysaccharides is extremely high.

(4). **Predictability of the Art:**

The function of any polysaccharide having a molecular weight from about 1,000 to about 50,000 daltons is highly unpredictable. In fact, polysaccharides having molecular weights from about 1,000 to about 50,000 daltons have different structures and thus different chemical and physical properties. It is well established that "the scope of enablement varies inversely with the degree of unpredictability of the factors involved," and that physiological activity is generally considered to be an unpredictable factor. See *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Thus, the state of the art is highly unpredictable.

(5). **Breadth of the Claims:**

The complex nature of the subject matter of this invention is greatly exacerbated by the breadth of the claims. The claims encompass a low viscosity glucomannan composition comprising glucomannan and an edible viscosity lowering polysaccharide.

(6). **Direction or Guidance Presented:**

The guidance given by the specification as to any viscosity lowering polysaccharide having a

molecular weight from about 1,000 to about 50,000 daltons is limited.

The disclosure of a maltodextrin, hydrolyzed guar gum, and inulin is adequate (examples 1, 2, 4, and 5, pages 14-16).

(7). **Working Examples:**

The working examples in the specification show the effect of maltodextrin on konjac viscosity (examples 1 and 2, pages 14-15). The working examples in the specification also show the effect of hydrolyzed guar gum on konjac viscosity (example 4, pages 15-16). The working examples in the specification further show the effect of inulin on konjac viscosity (examples 5, page 16).

Furthermore, the different polysaccharides having a molecular weight from about 1,000 to about 50,000 daltons have different structures and thus different chemical and physical properties. Therefore, the invention may not work with all polysaccharides herein claimed.

(8). **Quantity of Experimentation Necessary:**

The specification fails to provide sufficient support of any polysaccharide having a molecular weight from about 1,000 to about 50,000 daltons, other than maltodextrin, hydrolyzed guar gum, and inulin. As a result, one of skill in the art would be forced to perform an exhaustive search for the embodiments of any polysaccharide having the function recited in the instant claim suitable to practice the claimed invention.

Therefore, in view of the Wands factors, e.g. the predictability of the art, the amount of direction or guidance, and the lack of working examples discussed above, a person of skill in the art would not be able to fully practice the instant invention without *undue experimentation*.

***Response to Arguments***

3. Applicant's arguments, see "Remarks" filed on December 10, 2007, with respect to "Rejections under 35 U.S.C. § 112, 1<sup>st</sup> paragraph" have been fully considered and are not persuasive.

Applicants have provided an affidavit that enables the claims to include the following additional viscosity lowering polysaccharides: Larch Gum, Gum Arabic, and Benefiber. However, Applicants are still not enabled for any other polysaccharide having molecular weight from about 1,000 to about 50,000 daltons.

Thus the rejection under 35 U.S.C. § 112, 1<sup>st</sup> paragraph to claims 35-48 have been maintained.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 35-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartigan et al. (US 5,709,896 as cited in the IDS) in view of Greenberg (US 5,260,279).

Hartigan et al. teach reduced-fat food aqueous dispersions comprising a sugar syrup and a MCC-GUM (abstract and column 1, lines 57-59). The dispersion also contains fat, which may be from milk (column 1, line 66; and column 17, line 50). The MCC-GUM is konjac flour (column 2, line 41). An edible material may also be incorporated into the MCC-GUM, which is a polysaccharide of natural or synthetic origin, namely maltodextrin, guar gum, and mixtures (column 2, lines 43-44, 51-52, and 55-56). The sugar is inulin or maltodextrins having a dextrose equivalent (DE) of 10 and 15 (column 3, lines 51-54). The reduced-fat aqueous dispersions are used in yogurt, fudge, pretzels, cookies, and cakes (abstract; and column 6, lines 11, 13, 17, and 20).

It is noted that Applicants have defined “viscosity lowering compound” as “polysaccharides and proteins which when added to a glucomannan dispersion can lower the viscosity of that dispersion” (page 6, lines 13-15 of the specification). The Applicants have further identified “maltodextrin, inulin, and hydrolyzed guar gum” as examples of viscosity lowering polysaccharides (page 6, lines 15-17 of the specification). Since Hartigan et al. teach such polysaccharides, namely maltodextrin, guar gum, and inulin, the limitation of viscosity lowering polysaccharides in instant claims 35-48 have been met (column 2, lines 43-44, 51-52, and 55-56; and column 3, lines 51-54).

It is noted that Hartigan et al. teach the dispersion contain fat, which is from milk (abstract and column 1, lines 57-59). It would be obvious that milk fat is derived from milk and thus the aqueous dispersion of Hartigan et al. may be in an aqueous medium such as milk.

It is also noted that Hartigan et al. teach konjac flour as the MCC-GUM and that maltodextrin, an edible material, may be incorporated into the MCC-GUM (column 2, line 41,

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43-44, and 52). Accordingly, the weight of the konjac flour-maltodextrin is from about 0.2 to about 6 percent by weight, which meets the limitations of claims 37 and 40 (column 1, lines 64-65).

It is further noted that Hartigan et al. teach various polysaccharides, e.g. inulin and maltodextrin, which meet the limitations of claim 38 (column 2, lines 52 and 55). Because claim 38 is dependent on claim 35, the inulin and maltodextrin taught by Hartigan et al. also meet the limitation of polysaccharide having a molecular weight of from about 1,000 to about 50,000 daltons as recited in claim 35.

Regarding the amount of inulin as recited in claim 42, Hartigan et al. teach various polysaccharides, e.g. inulin and maltodextrin, which meet the limitations of claim 42 (column 2, lines 52 and 55). Thus it would be obvious to the skill artisan that the amount of inulin provided in the composition can be adjusted to contain from about 0.5% to about 30% by weight inulin as recited in claim 42.

Regarding a fat-containing food product as recited in claim 44, it is noted that Hartigan et al. teach a reduced-fat food aqueous dispersion (abstract). It would be obvious that reduced-fat food products such as the invention of Hartigan et al. still contain fat. Thus the reduced-fat food of Hartigan et al. is a fat-containing food product.

Regarding shortening as recited in claim 47, it is noted that shortening is defined in the art as an edible fat used to shorten baked goods. Because Hartigan et al. teach fat, namely milk fat, and that the reduced-fat food aqueous dispersion can be used in baked goods such as cookies and cakes (column 5, lines 19-21; and column 6, line 17), it would be obvious that the fat component may be used as a shortening in preparing such baked goods.

Hartigan et al. does not teach hydrolyzed guar gum.

Greenberg teaches low-viscosity enteral and medical foods which contain fiber, especially soluble fiber (column 1, lines 8-10). The composition of Greenberg contains hydrolyzed guar gum that is of 20,000 to 30,000 molecular weight (column 2, lines 27 and 33-34). It is noted that Greenberg acknowledges the molecular weight range of the hydrolyzed guar gum may vary and thus it would be obvious to the skilled artisan that the amount of hydrolyzed guar gum provided in the composition can be adjusted to be from about 1% to about 20% by weight as recited in claim 41.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the reduced-fat food aqueous dispersion of Hartigan et al. to contain hydrolyzed guar gum because the nutritional product of Wolf et al. teach konjac flour and hydrolyzed guar gum or inulin and according to Simon et al., konjac flour and hydrolyzed guar gum or inulin can be used in nutritional products.

Accordingly, absence the showing of unexpected results, it would have been obvious to a person of skill in the art at the time of the invention to employ the compounds of Hartigan et al. to contain hydrolyzed guar gum with the expectation of obtaining at least an additive effect, because konjac flour, maltodextrin, inulin, and hydrolyzed guar gum are all known to be used in a food composition as shown by Hartigan et al. and Greenberg, respectively.

It is noted that "It is obvious to combine individual compositions taught to have the same utility to form a new composition for the very same purpose" and "It is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third

composition that is to be used for the very same purpose". *In re Kerkhoven*, 626 F.2d 846, 205 U.S.P.Q. 1069 (C.C.P.A. 1980).

### ***Conclusion***

5. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlic K. Huynh whose telephone number is 571-272-5574. The examiner can normally be reached on Monday to Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gollamudi S Kishore, Ph.D/  
Primary Examiner, Art Unit 1612

ckh